IN THE

Supreme Court of the United States

ALPHAPHARM PTY., LTD. and GENPHARM INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This Court has long held that a party cannot be punished for what it was lawfully entitled to do. In spite of this fundamental rule-of-law, that is precisely what happened here. The district court punished Alphapharm for what it was lawfully entitled to do, and in the process may have gutted the underlying purpose of the Hatch-Waxman Act. In *BMW of North America Inc. v. Gore*, 517 U.S. 559, 573-74 (1996), this Court held that a fact finder (in that case, an Alabama state jury) has no power to punish a litigant for conduct that is lawful in that or other jurisdictions. The jury there had awarded $4 million in punitive damages against the automobile company BMW for repairing and repainting minimally damaged cars without notice to prospective buyers. But BMW could have no reason to believe that its conduct would subject it to sanctions in either Alabama or any of the other 49 states. Finding that the Alabama award constituted a due process violation, this Court reversed and remanded.

Here the Court faces a closely analogous set of facts. Alphapharm Pty., Ltd. and Genpharm Inc. (collectively "Alphapharm") challenged U.S. Patent No. 4,687,777 ("the '777 patent") under the Hatch-Waxman Amendments ("Hatch-Waxman") to the Food, Drug, and Cosmetic Act by certifying to the FDA that the compounds claimed in that patent were obvious. Hatch-Waxman allows such challenges if the patentee is provided notice of the challenge with a detailed statement of the legal and factual bases in support. Alphapharm provided that notice by pre-suit letter ("Notice Letter"), and explained that the '777 patent

was obvious over two particular prior-art references. Following trial, the district court rejected the challenge and ruled the '777 patent nonobvious. But the district court went further, finding that the challenge was in bad faith under the patent act's exceptional-case provision. The district court's principal basis for this finding was Alphapharm's reliance on additional prior-art references it adduced during pre-trial discovery. This was ***standard*** litigation conduct in a patent case—indeed in any case. Alphapharm had no cause to believe using information obtained through discovery at trial would subject it to sanctions. Just as in *Gore*, Alphapharm was punished for lawful conduct. Does the court's award of $5.4 million against Alphapharm penalize it for engaging in standard litigation conduct, and thus deprive Alphapharm of due process of law?

PARTIES TO THE PROCEEDING

This case arises from two separate challenges to the validity and enforceability of the '777 patent arising under Hatch-Waxman. *See* 21 U.S.C. § 355 et seq. Hatch-Waxman allows generic pharmaceutical companies, such as Alphapharm, to certify their intent to seek marketing approval of a brand-name drug, so long as they certify that any patent listed by the brand name as covering that drug, or a method of its use, is not infringed, invalid, or unenforceable. In return, Hatch-Waxman allows the patent holder to file an infringement proceeding against the company seeking such marketing approval.

Alphapharm certified that the compounds claimed in the '777 patent were obvious, and thus invalid, over the prior art. Mylan Laboratories, Inc. (n/k/a Mylan Inc.), Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively, "Mylan") also certified that the '777 patent was obvious. Respondents Takeda Chemical Industries, Ltd. and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda") sued Alphapharm and Mylan in the Southern District of New York for infringement of the '777 patent.

The case was tried in January 2006 before the bench. The district court ruled that the '777 patent was valid and enforceable. On September 20, 2006, the district court ruled the case exceptional, finding that Takeda was entitled to recover its attorneys' fees incurred to respond to these challenges. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 459 F. Supp. 2d 227, 252 (S.D.N.Y. 2006). (A27-80.) On March 21, 2007, the district court quantified the amount of the fees award, which

the court apportioned between Alphapharm and Mylan. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, Nos. 03-8253, 04-1966, 2007 WL 840368, at *1 (S.D.N.Y. Mar. 21, 2007). (A81-117.) Alphapharm and Mylan appealed, and the Federal Circuit affirmed the award of fees on January 23, 2009. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 549 F.3d 1381, 1391 (Fed. Cir. 2008) (A1-26.)

CORPORATE DISCLOSURE STATEMENT

The parent corporation and/or publicly held company that owns 10% or more of the stock of Petitioners Alphapharm Pty., Ltd. and Genpharm Inc. is Mylan, Inc. (Since the trial and appeal, Mylan, Inc. acquired Alphapharm Pty., Ltd. and Genpharm Inc.)

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OPINIONS BELOW

The Federal Circuit's opinion is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 549 F.3d 1381 (Fed. Cir. 2008) and is set forth in the appendix at A1-26. The opinion of the United States District Court for the Southern District of New York finding the case exceptional is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 459 F. Supp. 2d 227 (S.D.N.Y. 2006) and is set forth at A27-80. The district court's quantification of the attorneys' fees Alphapharm was ordered to pay is reported at *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.* Nos. 03-8253, 04-1966, 2007 WL 840368 (S.D.N.Y. Mar. 21, 2007), and is set forth at A81-117.

JURISDICTION

The Federal Circuit entered judgment on December 8, 2008. (A1.) The Federal Circuit denied Alphapharm's petition for rehearing en banc on January 23, 2009. (A118-19.) This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

The district court sanctioned Alphapharm $5.4 million in Takeda's attorneys fees because, in the district court's view, Alphapharm's challenge to the '777 patent was baseless. This finding was erroneous and deprived Alphapharm of due process. The district court concluded baselessness largely because Alphapharm did not rely solely on the position and proof it first offered in its pre-suit Notice Letter. Instead, Alphapharm—like any litigant would—relied at trial on information it obtained from Takeda from discovery under the Federal Rules of Civil Procedure. No other court had ever concluded that a deviation in legal theories or facts first alleged in a pre-suit Notice Letter would subject the patent challenger to pay the other side's attorney's fees. To the contrary, district courts have treated the requirement of such pre-suit notice simply as a means by which a patentee can protect his interests by conducting further investigation and, if necessary, filing suit. Alphapharm could never have foreseen that its lawful reliance on the Federal Rules of Civil Procedure would subject it to sanctions. Nor could Alphapharm have foreseen the result during the pendency of the case. Takeda never brought—indeed could not bring—a motion for sanctions pursuant to Rule 11 of the Federal Rules of Civil Procedure. Nor did Takeda (or the district court sua sponte) bring a sanctions motion for vexatious conduct under 28 U.S.C. § 1927. The failure to do so undermines the legitimacy of the district court's new-found findings of "litigation misconduct." (A50-63.)

Finally, the district court improperly imputed to Alphapharm knowledge of what the district court found

only after hearing Takeda's evidence—based largely on information until then withheld from the public—at trial. According to the district court, Takeda presented compelling evidence of commercial success of Actos®. Because Alphapharm knew that Actos® enjoyed significant sales, the court reasoned that Alphapharm should have addressed and refuted this evidence in its *pre-suit* Notice Letter. But Alphapharm had no obligation to do so under the law. Commercial success is an affirmative defense, which the patentee raises, not the challenger. Such defenses require extensive discovery and cannot be intelligently addressed before discovery is taken. For example, the defense of commercial success requires the patentee to demonstrate that the product covered by the patent enjoys success in the marketplace because of its patented features rather than factors such as clever marketing or brand recognition. To have addressed the issue, Alphapharm would have needed information on what factors other than patented features may have influenced sales, such as market position, distribution rights, salespersons, and marketing budgets. This information is not in the public domain, but rather rests exclusively with Takeda.

Left to stand, the district court's award (and the Federal Circuit's decision to affirm) seriously undermine the incentives Congress intended when it passed the Hatch-Waxman Act. The legislation was supposed to encourage generic pharmaceutical companies to "make lower cost generic drugs available more quickly." H.R. Rep. No. 108-181, at 9 (2003). But generic challengers may now, in effect, be limited to the allegations made in their pre-suit Notice Letter,

affording only the patentee the advantages of discovery. Moreover, generic challengers must now speculate on each and every potential defense a patentee might raise, foregoing otherwise valid challenges to a patent for fear of having sanctions imposed at the end of the case. These quite substantial policy considerations favor granting certiorari.

I. The District Court Decision Finding the Case Exceptional

Following limited written submission from the parties, the district court found the case "exceptional." (A30.) Several major legal errors led the district court to this conclusion.

Most relevant here, the district court erroneously believed Alphapharm's Notice Letter—***a presuit document***—forever barred Alphapharm from aiding its trial presentation with the discovery it had obtained from Takeda. According to the district court:

> What is truly exceptional here is the cascade of attacks each defendant made on the '777 patent. If the defendants had simply pursued the theories presented in their [Notice Letters], the cost of litigation would have been far lower and a simple award of the lodestar calculation may have been warranted . . . In each instance, the [Notice Letter] was so lacking in merit that it was entirely abandoned by the time of trial.

(A109.) But the court was simply wrong in concluding that Alphapharm abandoned the allegations it made in

its Notice Letter. Throughout the case, Alphapharm never abandoned the assertions it made in the Notice Letter that the compounds claimed in the '777 patent were obvious over an extremely close prior-art compound. The same "trial by Notice Letter" error led the district court to dismiss Alphapharm's reliance on other Takeda patents and file histories which became relevant during the course of discovery. According to the district court, "Alphapharm was under an obligation to identify these two references in its [Notice Letter.]" (A61.) But 35 U.S.C. § 282 only requires a patent challenger to identify the prior art it intends to rely on ***30 days prior to trial***—not at the outset of a patent case.

The district court also faulted Alphapharm for not addressing a defense that was never raised by the patentee before the Patent Office, namely so-called "commercial success." Generally speaking, a challenger alleging obviousness need only address affirmative defenses in a patent case (known as secondary considerations of nonobviousness) to the extent these defenses were raised before the Patent Office. *Cf. Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) (acknowledging presumption of validity based on information before the examiner). In the Notice Letter, Alphapharm addressed the only defense that the Patent Office considered, unexpected results. Other affirmative defenses are raised in litigation by the patentee. But the district court faulted Alphapharm nonetheless: "The most important fact concerning non-obviousness, the significant commercial success of Actos® was well known to Alphapharm and required no discovery. The Statement was deficient in this regard

as well." (A50; *see also* A49; A62.) The district court was simply mistaken that this issue "required no discovery." *See, e.g.*, *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150-51 (Fed. Cir. 1983) (sales figures alone, without considering other evidence such as market share, growth in market share is insufficient to establish commercial success). The relevance of commercial success to obviousness is only present where the patentee demonstrates that the patented features of the invention—rather than marketing, advertising, or brand positioning—are responsible for the success of a product the patent covers. Alphapharm had no access to Takeda's marketing and advertising documents to address the issue intelligently before the lawsuit began.

Alphapharm appealed the district court's validity ruling to the Federal Circuit.

II. The Federal Circuit's Affirmance

The Federal Circuit affirmed, affording broad deference to the factual findings of the district court. "Given the district court's familiarity with the parties and the issues and its thorough discussion of Alphapharm's certification letter and litigation strategy, we cannot say that the court committed clear error in finding this was an exceptional case . . . ." (A13.)

The Federal Circuit acknowledged that the district court faulted Alphapharm for buttressing its Notice Letter arguments with discovery obtained from Takeda. (A10) (noting "we do not believe that the district court faulted Alphapharm simply for changing its obviousness theory at trial from the theory advanced in the

Paragraph IV letter.") But the Federal Circuit overlooked the fact that the district court sanctioned Alphapharm for conduct wholly proper in a Hatch-Waxman case—indeed in any—case. No district court had ever held that a patent challenger could be sanctioned for availing itself of the discovery obtained under the Federal Rules of Civil Procedure. Nor did the Federal Circuit address the sanctions the district court imposed because Alphapharm did not address the issue of the commercial success of Actos®, a ***defense*** to a claim of obviousness irrelevant in an opening pleading.

Alphapharm moved for a petition for rehearing en banc but the Federal Circuit denied those petitions. (A118-19.)

REASONS FOR GRANTING THE PETITION

I. PUNISHING ALPHAPHARM FOR PROPER CONDUCT VIOLATED ITS RIGHT TO DUE PROCESS OF LAW

"To punish a person because he has done what the law plainly allows him to do is a due process violation of the most basic sort." *See Bordenkircher v. Hayes*, 434 U.S. 357, 363 (1978). The district court imposed just such an unfair punishment on Alphapharm, ordering it to pay $5.4 million in sanctions for ***standard*** litigation conduct. Alphapharm had no prior warning that the structural obviousness law it relied on would be ignored by the district court and the Federal Circuit. Nor could Alphapharm know that using discovery obtained from Takeda under the Federal Rules would trigger an award of sanctions for allegedly "shifting theories." There was

never any shift in Alphapharm's position. A party's use of trial proofs obtained in discovery hardly amounts to conduct that is either egregious or vexatious.

This Court faced a similar situation in *BMW of North America v. Gore*, though in the context of the relationship between the federal government and the states. 517 U.S. at 562-63. In *Gore*, Gore sued BMW for compensatory and punitive damages alleging that BMW's failure to disclose the repainting of his new car and pre-delivery damage constituted fraud under Alabama law. *Id.* at 563. An Alabama jury found BMW liable for compensatory damages of $4,000, but also assessed $4 million in punitive damages. *Id.* at 565. The trial court refused to set the punitive damages aside on due process grounds. The Alabama Supreme Court affirmed, but reduced the punitive damages award to $2 million because the jury had improperly computed the amount of punitive damages. *Id.* at 566-67. This Court reversed, holding that Alabama did "not have the power . . . to punish BMW for conduct that was lawful where it occurred and that had no impact on Alabama or its residents. Nor may Alabama impose sanctions on BMW in order to deter conduct that is lawful in other jurisdictions." *Id.* at 572-73.

Just as in *Gore*, the award of $5.4 million amounted to "a punitive sanction that is tantamount to a severe criminal penalty" for otherwise lawful conduct. *Id.* at 585. This Court should grant Alphapharm's petition and reverse the district court's award.

A. Alphapharm Could Not Know That Using Discovery Would Lead to Sanctions

The decision to use discovery to enhance a Hatch-Waxman case first delineated in a presuit Notice Letter is anything but "exceptional." *Aptix Corp. v. Quickturn Design Sys.*, 269 F.3d 1369, 1375-76 (Fed. Cir. 2001) (holding exceptional case because of ***unconscionable*** conduct during discovery). Generic challengers—forced to certify the invalidity of a patent without the benefit of access to confidential documents—must use discovery to develop their cases. Indeed, patent law specifically envisions that outcome. Section 282 requires a challenger to notify the patentee of the prior art the challenger expects to rely on—not at the outset—but ***within 30 days of the trial itself***. 35 U.S.C. § 282. Alphapharm complied with the statute. The district court's decision to sanction Alphapharm for relying on additional prior art not only renders that statute nugatory, but unfairly penalized Alphapharm for following the rules applicable to ***all*** patent cases.

Rules 26 through 37 of the Federal Rules of Civil Procedure provide to ***both*** parties in a litigation broad discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." Fed. R. Civ. P. 26(b)(1). The district court awarded sanctions against Alphapharm for utilizing these discovery rules to respond to Takeda's nonobviousness contentions. While the Hatch-Waxman Amendments require a pre-suit "detailed statement" from a generic challenger, that statement does not limit the challenger from amplifying its case through discovery. Indeed, Hatch-Waxman cases do not differ from other patent

cases. *Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007). Patent challengers as well as patentees must be able to develop facts and refine legal theories. *See, e.g., O2 Micro Int'l Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1365 (Fed. Cir. 2006) (discovery in all patent cases "allows the defendant to develop facts to support its defenses").

1. Generics often prevail on legal theories first presented after discovery

Moreover, it is common for a generic challenger, following access to the patentee's confidential documents, to use the evidence gained in discovery to refine or alter its invalidity defenses. For example, in *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 960 (Fed. Cir. 2001), the generic challenger certified as to the invalidity of the patent covering the drug Prozac®. But the winning invalidity theory—double patenting—was developed during discovery. *Id.* at 969-72. In other instances, the generic challenger prevailed on a previously unasserted invalidity theory. For example, in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1303 (Fed. Cir. 2007), involving the drug Altace®, the generic challenger prevailed on an obviousness defense different from that asserted in its pre-suit notice letter, and developed during discovery. *Id.* at 1302-03. Generic challengers prevailed in similar ways in challenges to the drugs Ditropan XL® and Imodium Advanced®. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295-97 (Fed. Cir. 2006); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370 (Fed. Cir. 2003).

2. Alphapharm could not have known that adding defenses would subject it to sanctions

The Hatch-Waxman Act requires generic challengers to serve a pre-suit Notice Letter so that a patent challenge is sufficiently "concrete" to secure federal jurisdiction. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). Before the district court's finding of exceptional case here, no court had ever held that a patent challenger was bound at trial by the allegations in the Notice Letter. Rather, the Notice letter need only alert the patentee to the possibility of infringement by the generic applicant so that "the patent owner can protect its interest in its patents by filing a patent-infringement action." *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99-8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000). Indeed, since the award, at least one other court has squarely refused to accept the proposition that deviating from a notice letter at trial renders the case exceptional under § 285. In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007), generic challenger Teva's notice letter failed to make out a prima facie case of invalidity. And just as Alphapharm is alleged to have done, Teva dropped certain arguments at trial and adduced additional prior art after having the benefit of discovery. *Id.* at *10-11. Yet, the court there refused to impose sanctions. *Id.* at *11.

B. Alphapharm Had No Reason to Attempt to Rebut Potential Affirmative Defenses in the Notice Letter

The Federal Circuit noted that the district court correctly found that Alphapharm's Notice Letter would amount to litigation misconduct if it were baseless and failed to establish a prima facie case of invalidity. (A13.) But the district court sanctioned Alphapharm in part because Alphapharm's Notice Letter failed to address commercial success—a potential ***defense*** to Alphapharm's obviousness assertions. (A49-50.) The Federal Circuit panel failed to address this error.

First, the secondary indicia of nonobviousness are simply not part of a prima facie case of invalidity. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006) (holding that the secondary indicia, including commercial success, ***rebutted*** any showing of prima facie obviousness). The patentee—not the challenger—bears the burden on this issue. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). The law did not require Alphapharm to anticipate and rebut every potential patentee defense in its Notice Letter using only publicly available information.

Moreover, Alphapharm could hardly have acted in bad faith for failing to address an issue it could not reasonably address without discovery. Commercial success is relevant only where "the [patentee's] sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the

patented subject matter." *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). Alphapharm could not possibly determine what was driving the sales of Actos® until discovery was had. Such information is maintained as confidential. Notably, Alphapharm's expert economist—armed with the information Alphapharm obtained in discovery—testified that non-patented features, including market forces, an aggressive marketing campaign, and unusual giveaways accounted for the qualified success of Actos®. (SA1-48.)

II. REVERSAL OF THE RULING WILL RESTORE A LEVEL PLAYING FIELD BETWEEN GENERIC AND BRAND PHARMACEUTICAL COMPANIES

Alphapharm, and its co-defendant Mylan will not be the only parties affected by the district court's sweeping ruling, now affirmed. The award of sanctions on these grounds cannot help but to chill and deter future generic filings. Generic companies may not file a paragraph IV certification unless confident that the case could be won ***without pretrial discovery***. The purpose of the Hatch-Waxman Amendments—to speed delivery of inexpensive medicine to patients—will be seriously undermined. S. Rep. No. 105-36(I), at 125 (1997).

Those generics that do mount a patent challenge will be forced to self-censor bringing additional theories to bear at trial no matter what the other side's confidential documents reveal. Trials are a search for the truth, not a rote presentation limited to publicly available documents. *See Portuondo v. Agard*, 529 U.S. 61, 73 (2000). Nor should a trial have the same breadth as the pretrial discovery. *See* Fed. R. Civ. P. 26(b) advisory

committee notes (the 1946 amendments "make clear the broad scope of examination and that it may cover not only evidence for use at trial but also inquiry into matters in themselves inadmissible . . . .").

The ruling will also create perverse incentives. The district court chose to sanction Alphapharm for dropping a theory based on what it had learned in discovery (A47-48.) The Federal Circuit's affirmance of that ruling will now only encourage generic challengers to put in and maintain every possible argument at trial, for fear that narrowing the issues will be used against them in a later fees application.

Left to stand, the court's ruling arms the brand-name company with the full use of the broad discovery set forth in the Federal Rules of Civil Procedure while forcing a generic company to subject itself to sanctions for availing itself of the same Rules. Such a result is clearly contrary to law. "[T]here is and should be no difference in the standards applicable to patentees and infringers who engage in bad faith litigation." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990). Reversing the district court's ruling will restore a level playing ground. *See Doubleday & Co. v. Curtis*, 763 F.2d 495, 503 (2d Cir. 1985) (reversing dismissal of claim where dismissal "violated the spirit of both the United States Constitution [due process clause] and the Federal Rules of Civil Procedure [Rule 8(c)].").

CONCLUSION

Alphapharm respectfully requests that this Court grant the petition for a writ of certiorari, and reverse the judgment of the Federal Circuit.

Dated: May 26, 2009

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